



Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
--------------------	-------------	-----------------------	------------------

09/254,870 08/16/99 SPENGLER

EXAMINER
D 147-183PCT

HM12/0305

COOPER & DUNHAM
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

ART UNIT	PAPER NUMBER
----------	--------------

PATTERSON, C

DATE MAILED:
1652

03/05/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/11/00

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-48 is/are pending in the application
Of the above, claim(s) 25-35, 37, 38, 40, 42-48 is/are withdrawn from consideration
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-16, 44 is/are rejected.
☒ Claim(s) 17-24, 36, 39 is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.
☐ received in Application No. (Series Code/Serial Number) _____
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 1 Page
☐ Interview Summary, PTO-413
☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES..

Applicant's election with traverse of Group II in Paper No. 14 is acknowledged. The traversal is on the ground(s) that 35 USC § 121 states the two inventions must be independent and distinct and that the Groups I-VI are not independent. Furthermore they argue that the "restriction of Group I and II, at a minimum, should be withdrawn, since two or more independent and distinct inventions have not been claimed and there would not be a serious burden on the Examiner if restriction were not required". Applicants also maintain that MPEP § 803 requires that the examiner must examine the application if there is not a serious burden.

This is not found persuasive because in MPEP § 802.01 the meaning of "independent" and "distinct" is discussed, along with a discussion of the legislative history of these terms in patent law. It is concluded in MPEP § 803 that restriction is proper when the inventions "are either independent (MPEP § 806.04 - §806.04(i)) or distinct (MPEP § 608.05 - § 806.05(i)) (emphasis added). As to the restriction being a serious burden, it is maintained that it would be a serious burden to search all of the inventions. The patent classification is only one of the areas searched with non-patent literature being perhaps most important in this subject matter. Furthermore, such things as 35 USC § 112 first paragraph matters enter into the burden of examining all of the groups.

The argument as to rejoinder of Groups I and II is agreed with and therefore Groups I and II (claims 1-24, 36, 39 and 41) will be examined.

The requirement is still deemed proper and is therefore made FINAL.

Claims 25-35, 37-38, 40 and 42-48 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 14.

In their amendment to the first paragraph of the specification, applicants make reference to PCT/EP97/05198 as the 35 USC § 371 priority application for this application but do not make reference to 08/718,661, which is also claimed in the oath as having 35 USC § 120 priority. A statement to this effect must be included in the first paragraph along with an indication whether this is a continuation, continuation-in-part or divisional application. Apparently this application is a continuation-in-part of the parent.

The Information Disclosure Statement filed March 15, 1999 had a PTO-1449 attached, a signed copy of which is enclosed with this action. However, approximately as many documents as are listed on the 1449 were also apparently submitted with no 1449. If applicants wish to have these documents considered they should submit a PTO-1449 listing them.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 and 19-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 5,876,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims claim essentially the same thing as the claims of the patent, with only minor differences in wording.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 12 is rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility. The claim is drawn to a nucleic acid which encodes an inactive tumor suppressor. There is no apparent utility for this nucleic acid.

Claim 41 is rejected under 35 U.S.C. § 101 because it is drawn to non-statutory subject matter. Use claims are not allowed in U.S. patent practice, The claim should be drawn to a method with distinct steps.

Claims 1-2, 4, 7, 12, 36 and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "nucleic acid molecules hybridizing to a nucleic acid molecule as defined in (a) or (b)". There is no indication of stringency nor size. Almost any nucleic acid will hybridize to another if the stringency is low enough and/or if it is small enough.

Claim 2 is indefinite in the recitation of "optionally" on line 17. It is also indefinite in the recitation of "pool(s)" twice and "vector(s)" once. It is not clear whether the singular or plural is desired.

Claim 4 is indefinite in the recitation of "the peptide PACAP". To the ordinary artisan reading this claim "PACAP" would indicate "Pro-Ala-Cys-Ala-Pro". Apparently "pituitary adenylate cyclase activating peptide" was intended.

Claim 7 is indefinite in the recitation of "MMTV". Apparently "mammary mouse tumor virus" was intended.

Claim 12 is indefinite in the recitation of "hybridizes to a nucleic acid molecule of claim 1". As noted *supra*, if a molecule is short enough and/or if the hybridization conditions have a low enough stringency, almost any molecule will hybridize with another. It is also confusing and indefinite in the recitation of "said mutated version" on line 2. The term does not have antecedent basis in claim 1.

Claim 20 is indefinite in the recitation of "and/or". It is not clear whether the vector must be expressed in both prokaryotic and eukaryotic cells or only one.

Claim 36 is indefinite in the recitation of "hybridizing conditions" on line 5 and "hybridized" on line 6. As noted *supra*, almost any nucleic acid will hybridize to another if it is short enough or the stringency of the hybridization is low enough.

Claim 41 is indefinite in the recitation of "and/or" on line 3. It is not clear from the instant recitation whether the cumulative or alternative is desired.

Claim 41 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is drawn to using the 15 nucleotide long nucleic acid molecule of claim 18 to treat, prevent or delay reoccurrence of a disease in a subject. The specification does not teach that this 15 nucleotide long nucleic acid molecule has ever been used to treat, prevent or delay reoccurrence of a disease in a subject and therefore there is nothing that would make one of ordinary skill in the art believe this would work.

The instant claims are free of the prior art of record. Claims 17-24, 36 and 39 are objected to as being dependent upon a rejected base claim.

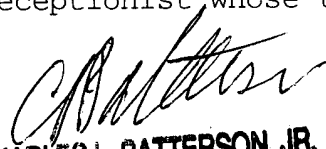
Abdollahi, et al. (A & B) are cited as of interest. Abdollahi, et al. (A) teaches a human tumor suppressor protein that is 99.8% identical with SEQ ID NO:17 (there is only 1 amino acid difference). It also teaches the gene. However, the reference cannot be used against claims 1-16 because this claim has priority back to the parent application and it cannot be used against claim 17 (which only has priority back to the 371 PCT) because the claim is limited to SEQ ID NO:16 or 17. The limitations of claim 17 do not allow one to read into the claim the limitation of claim 1 that it hybridizes to the nucleic acid sequences of claim 1, in which case the reference could have been used. Abdollahi, et al. (B) is cited as of interest in that it teaches the tumor suppressor protein and gene from rat.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., Ph.D. whose telephone number is (703) 308-1834. The examiner can normally be reached on any day of the week from 7:30 AM until 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Patterson
March 2, 2001


CHARLES L. PATTERSON, JR.
PRIMARY EXAMINER
0081 2001 03 02
PRIMARY EXAMINER
CHARLES L. PATTERSON, JR.